

REMARKS

The Office Action mailed July 17, 2003 has been received and carefully considered.

Initially, it is respectfully submitted that claim 24 is mistakenly withdrawn from examination.

Claims 21, 30 and 43 were objected to due to awkward wording or as depending from a rejected claim. These objections have been addressed through amendment to the claims.

Claims 2, 11-13, 16, 25,-29, and 38-41 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

Claims 11-13, 16, 42 and 44 were rejected under 35 U.S.C. §102(b) as anticipated by Garnitskij et al. (SU 1803032, based on an oral translation).

Claim 38 and 43 were rejected under 35 U.S.C. § 103(a) as being obvious over Garnitskij et al. in view of Modi et al. (U.S. 5,653,987).

The rejections, to the extent applied against the claims as amended, are respectfully traversed.

Objections

Claims 21 and 43 have been amended as suggested by the Examiner.

Claim 30, has been rewritten in independent format as suggested by the Examiner. Applicants thank the Examiner for the suggestions and have amended the claim to reflect the language found in the specification. Therefore, Applicants respectfully request the USPTO withdrawal the objections.

Rejections Under 35 U.S.C. § 112 ¶2

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 11-13, 16, 25-29 and 38-41 stand rejected under 35 U.S.C. § 112, second paragraph, as containing subject matter which fails to particularly point out and distinctly claim the invention. The USPTO states that “[t]here is insufficient descriptive support for the generic limitation ‘a condition requiring regulation of nicotine metabolism to continine’. Furthermore, the claimed methods require treatment of an unspecified disease and no evidence indicates that a treatable disease, other than nicotine use disorders (page 17 of specification), was known to

Applicant." (See, page 5 of Office Action). Applicants direct the Examiner's attention to page 18 of the application as filed as an example of where Applicants describe various non-tobacco related disorders which require regulation of nicotine metabolism to continine.

The methods and compositions of the invention in treating individuals with nicotine use disorders are also useful in the treatment and prophylaxis of diseases or conditions, including nicotine-related disorders such as opioid related disorders; proliferative diseases; cognitive, neurological or mental disorders; and other drug dependencies in the individuals. Examples of such underlying diseases or conditions include malignant disease, psychosis, schizophrenia, Parkinson's disease, anxiety, depression, alcoholism and opiate dependence. (See page 18, lines 25-31).

Therefore, Applicants submit the application as filed provides a clear description of various disorders other than nicotine-related disorders which require the regulation of nicotine metabolism to continine. Applicants have canceled claims 11-13, 16 mooting the rejection to the extent applied to those claims. Additionally, claim 2 now only depends from claim 17 which is an allowed claim.

Applicants respectfully request that this rejection be withdrawn in view of the claim amendments and above discussion of the specification as filed.

35 U.S.C. §102(b)

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicants submit that the cancellation of claims 11-13, 16, 42 and 44 moot the rejection by the Examiner.

The rejection is respectfully obviated.

35 U.S.C. §103(a)

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicants submit that the cancellation of claim 43 moots the rejection by the Examiner.

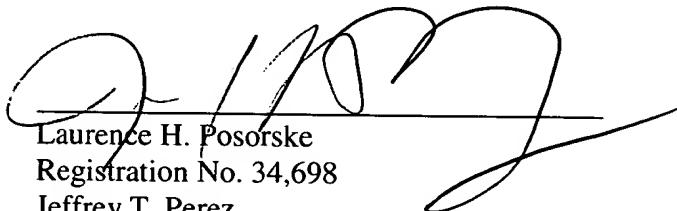
The rejection is respectfully obviated.

CONCLUSION

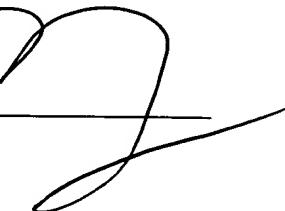
Applicants assert that the above-referenced application is in condition for allowance. Reconsideration and allowance of all pending claims is respectfully requested. Should any outstanding issues remain, the Examiner is invited to telephone the undersigned at 202-955-1500.

Respectfully submitted,

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